SEP 11 2009

K083536

1/2

BIOMÉRIEUX

510(k) SUMMARY

DensiCHEK™ Plus

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jolyn Tenllado Associate Staff Regulatory Affairs Specialist
Phone Number:	314-731-8386
Fax Number:	314-731-8689
Date of Preparation:	November 26, 2008

B. Device Name:

Formal/Trade Name:	DensiCHEK™ Plus
Classification Name:	Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645
Common Name:	DensiCHEK Plus

C. Predicate Device: DensiChek (K050002, VITEK 2 Compact)

D. 510(k) Summary:

DensiCHEK™ Plus is intended for use with the VITEK® and VITEK® 2 Systems to measure the optical density of a microorganism suspension. The instrument provides values in McFarland units, proportional to microorganism concentrations. The DensiCHEK Plus has applications as an *in vitro* diagnostic medical device.

The DensiCHEK Plus generates a McFarland value using basic colorimetry, which is a method of measurement that relates the amount of color in a transparent medium (liquid) to the amount of a particular substance in the liquid. In general the concentration of the substance being measured is proportional to the intensity of the color of the solution. The darker the color is, the higher the concentration. Absorbance (Abs) is a commonly used measure of the amount of light absorbed by the solution. Absorbance is given by:

$Abs = -\log T$ or $Abs = -\log (I_T/I_0)$

Where:

T = Transmittance

I_T = Intensity of light transmitted through the sample

I_0 = Intensity of light entering the sample

The DensiCHEK Plus measures the turbidity of the saline and microorganism suspension using a single wavelength, 580 nm. The absorption of light determines the McFarland value generated by the instrument. The more turbid the suspension is, the higher the McFarland standard measurement. The light source in the DensiCHEK plus is an LED that emits a narrow range of wavelengths, and an interference filter is used between the LED and the test tube (sample) to further narrow the wavelength to 580 nm. There are 2 calibration curves pre-programmed into the DensiCHEK Plus, one for glass tubes and one for plastic tubes. The absorbance is different for glass and plastic, therefore the laboratory technician using the DensiCHEK Plus must choose the appropriate tube type setting for the inoculum suspension based on whether it was prepared in a glass or plastic test tube. The instrument is first zeroed using a test tube filled with saline (blank). The technician then places the well-mixed organism suspension into the instrument and slowly rotates the test tube. The instrument will display a series of dashes followed by a McFarland reading.

DensiCHEK Plus demonstrated substantially equivalent performance when compared with the DensiChek in the performance equivalency study utilizing VITEK and VITEK 2 Identification and Susceptibility cards and systems. This device also demonstrated acceptable accuracy, repeatability (within instrument variability) and reproducibility (between instrument variability) during validation. The Premarket Notification (510[k]) presents data in support of DensiCHEK Plus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

SEP 11 2009

Ms. Jolyn Tenllado
Associate Director, Regulatory Affairs
bioMérieux
595 Anglum Road
Hazelwood, MO 63042

Re: k083536
Trade/Device Name: DensiPLUS™ Plus
Regulation Number: 21 CFR 866.1645
Regulation Name: Short-Term Antimicrobial Susceptibility Test System
Regulatory Class: Class II
Product Code: LON
Dated: September 9, 2009
Received: September 10, 2009

Dear Ms Tenllado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Linda Y. Poole, MS
for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):___K083536_____

Device Name: DensiCHEK™ Plus

Indications For Use:

The DensiCHEK™ Plus instrument is intended for use with the VITEK® and VITEK® 2 Systems to measure the optical density of a microorganism suspension. The instrument provides values in McFarland units, proportional to microorganism concentrations. DensiCHEK Plus is indicated for use with polystyrene and glass test tubes and the reading range is 0.0 - 4.0 McFarland. The DensiChek™ Plus has applications as an *in vitro* diagnostic device.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083536